PATTERSON BELKNAP WEBB & TYLER LLP
John D. Winter
1133 Avenue of the Americas
New York, New York 10036-6710
Telephone: (212) 336-2000
Attorneys for Defendants
Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc.
and Johnson & Johnson Pharmaceutical Research and Development, LLC

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

HERMAN MARKS,	:	
Plaintiff,	:	**ANSWER WITH AFFIRMATIVE DEFENSES**
v.	:	**CV 08 3552 (SWK)**
JOHNSON & JOHNSON, ORTHO-MCNEIL PHARMACEUTICAL, INC., and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC,	:	
Defendants.	:	

Defendants Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc. ("Ortho McNeil") and Johnson & Johnson Pharmaceutical Research and Development, LLC, by their attorneys Patterson Belknap Webb & Tyler LLP, answer plaintiff's complaint as follows:

INTRODUCTION

1. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the complaint.

2. Defendants admit that Defendant Ortho-McNeil Pharmaceutical, Inc. markets Levofloxacin in the United States, but deny the remaining allegations of paragraph 2 of the complaint.

3. Defendants admit that Levofloxacin was approved by the FDA for its labeled uses, but deny the remaining allegations of paragraph 3 of the complaint.

4. Defendants deny the allegations contained in paragraphs 4 through 6 of the complaint.

5. Defendants state that paragraph 7 of the complaint requires no response, but to the extent a response is required, it denies the allegations of paragraph 7 of the complaint.

JURISDICTION

6. Defendants admit that this Court has jurisdiction over this action as and that venue is proper as alleged in paragraphs 8 and 9 of the complaint.

PARTIES

7. Deny knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 10 of the complaint.

8. Defendants admit the allegations contained in paragraphs 11 through 13 of the complaint.

9. Defendants deny that they are registered to do business in New York, and admits the remaining allegations contained in paragraph 14 of the complaint.

FACTS

10. Defendants deny the allegations contained in paragraph 15 of the complaint. Defendants state that Levofloxacin is a synthetic broad spectrum antibacterial agent for oral and intravenous administration. The approved uses of Levaquin are stated in the package insert.

11. Deny each and every allegation contained in paragraphs 16 and 17 of the complaint.

12 Deny each and every allegation contained in paragraph 18 of the complaint but admit that different fluoroquinolones may differ in safety profiles.

13. Deny each and every allegation contained in paragraphs 19 of the complaint.

14. In response to paragraph 20 of the complaint, defendants admit that Levaquin was developed by Daiichi and Ortho-McNeil manufactures and markets Levaquin pursuant to a licensing agreement, but deny the remaining allegations contained in paragraph 20 of the complaint.

15. Deny each and every allegations contained in paragraph 21 of the complaint.

16. Admit the allegations contained in paragraph 22 of the complaint.

17. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 23 of the complaint.

18. Deny the allegations contained in paragraph 24 of the complaint. The chemical description of Levofloxacin is stated in the package insert.

19. Deny each and every allegation contained in paragraphs 25 and 26 of the complaint.

20 Deny the allegations contained in paragraphs 27, 28, 30, 31, 32, 34, 35, 36, 37, 38, 39, 40 of the complaint. The allegations are an incomplete description of the scientific knowledge regarding fluoroquinolones. Defendants state that the scientific literature and studies regarding fluoroquinolones speak for themselves. Defendants further state that the scientific literature and reported research on Levaquin form part of the basis of the marketing of the drug and the approval of it by the FDA, pursuant to the prescribing information.

21. Deny each and every allegation contained in paragraph 29 of the complaint.

22. In response to paragraph 33 of the complaint, defendants state that Ortho-McNeil submitted an NDA for Levaquin in 1995, and state that Ortho McNeil complied with all FDA labeling requirements at all times and made all appropriate reports to the FDA, and deny all remaining allegations contained in paragraph 33 of the complaint.

23. Admit that outcomes of tendon ruptures in persons over 60 are variable, and deny the remaining allegations contained in paragraph 41 of the complaint.

24. Deny the allegations contained in paragraph 42 of the complaint and state that the statements of any third parties are unverified heresay. The reports or statements of parties not associated with defendants speak for themselves.

25. Admits that Public Citizen did petition the FDA and that their petition speaks for itself. Defendants deny the remaining allegations contained in paragraph 43 of the complaint.

26. Deny each and every allegation contained in paragraph 44 of the complaint. Defendants affirmatively assert that Ortho-McNeil complied with all FDA labeling requirements and that the FDA approved label for Levaquin contains information on tendon rupture.

27. Deny each and every allegation contained in paragraph 45 of the complaint and further deny the statement and inaccurate and argumentative characterizations of the contents of the package insert. Defendants affirmatively asset that Ortho-McNeil complied with all FDA labeling requirement.

28. Admit that Ortho-McNeil began marketing Levaquin in the United States in 1997, and defendants are without sufficient information to admit or deny the remaining allegations contained in paragraph 46 of the complaint.

29. Deny each and every allegation contained in paragraphs 46 through 55 of the complaint.

30. In response to paragraphs 56 and 57 of the complaint, defendants affirmatively allege that foreign studies speak for themselves as to products studied and conclusion of such studies. Defendants deny the remaining allegations contained in paragraphs 56 and 57 of the complaint.

31. Defendants do not market Levaquin in Italy, and therefore deny the allegations contained in paragraph 58 of the complaint. Any foreign publications or statements from regulatory agencies speak for themselves.

32. Deny the allegations contained in paragraph 59 and 61 of the complaint. The allegations are an incomplete description of the scientific knowledge regarding fluoroquinolones and that the scientific literature and studies regarding fluoroquinolones speak for themselves. Defendants further state that the scientific literature and the reported research on Levaquin form part of the basis of the marketing of the medicine and the approval of it by the FDA, pursuant to the prescribing information.

33. Defendants do not market Levaquin in France, and therefore deny the allegations contained in paragraph 60 of the complaint. Any statements or reports of foreign regulatory agencies speak for themselves.

34. Defendants do not market Levaquin in Belgium and therefore deny the allegations contained in paragraph 62 of the complaint. Any statements or reports of foreign regulatory agencies speak for themselves.

35. Defendants admit that Ortho-McNeil changed the Levaquin label in 2001, but deny the remaining allegations contained in paragraph 63 of the complaint. Defendants affirmatively assert that Ortho-McNeil complied with all FDA labeling requirements at all times.

36. In response to paragraph 64 defendants affirmatively assert that the 1997 Levaquin label included a statement about tendon ruptures approved by the FDA. Defendants affirmatively assert that Ortho-McNeil complied with FDA labeling regulations, and deny the remaining allegations contained in paragraph 64 of the complaint.

37. In response to paragraph 65 defendants affirmatively assert that Ortho-McNeil changed the Levaquin label in 2002 in accordance with FDA regulations and with the approval of the FDA, but deny the remaining allegations contained in paragraph 65 of the complaint.

38. Defendants deny the allegations contained in paragraph 66 of the complaint, but admits that Daiichi shares post-marketing surveillance data with its licensees of Levaquin.

39. Defendants deny the allegations contained in paragraph 67 of the complaint.

40. Defendants deny the allegations contained in paragraph 68 of the complaint.. Defendants affirmatively assert that Ortho-McNeil complied with all FDA labeling requirements.

41. Defendants deny the allegations contained in paragraph 69 of the complaint but admit that Ortho-McNeil did not send a Dear Doctor letter in 2002. Defendants affirmatively assets that Ortho-McNeil complied with all FDA labeling requirements.

42. Defendants deny the allegations contained in paragraph 70 of the complaint.

43. Defendants deny the allegations contained in paragraph 71 of the complaint. Defendants do not market Levaquin in EMEA countries. Defendants further statesthat the statements or reports of foreign regulatory agencies speak for themselves.

44. Defendants do not market Levaquin in Europe, and therefore deny the allegations contained in paragraph 72 of the complaint. Defendants further state that the statements or reports of foreign regulatory agencies speak for themselves.

45. In response to the allegations contained in paragraph 73 of the complaint defendants admit that Sanofi-Aventis markets Levaquin in Europe.

46. Defendants deny the allegations contained in paragraph 74,75, 76, 77, 78, 79, 87 and 88 of the complaint as they do not relate to these defendants. Defendants further state that the studies regarding fluoroquinolones speak for themselves.

47. Defendants deny the allegations contained in paragraph 80, 81, of the complaint. Defendants state that the statements or reports of foreign regulatory agencies speak for themselves.

48. Defendants admit the allegations contained in paragraph 82 of the complaint.

49. Defendants deny the allegations contained in paragraph 83 through 86, 89, 90, 91, 92, 93, of the complaint.

50. Defendants deny the allegation contained in paragraph 94, 95, 96, of the complaint and put plaintiff to his strict burden of proving the allegations contained herein.

51. Defendants deny the allegations contained in paragraph 97, 98, 99, 100 of the complaint, and states that the petition speaks for itself.

52. Defendants deny the allegations contained in paragraph 101 of the complaint, and state that the 2007 label speaks for itself. Defendants affirmatively assert that Ortho-McNeil complied with all FDA labeling requirements.

53. Defendants deny the allegations contained in paragraph 102 of the complaint. Defendants affirmatively assert that Ortho-McNeil complied with all FDA labeling requirements.

54. Defendants deny the allegations contained in paragraph 103 of the complaint, and states that the label speaks for itself.

55. Defendants deny the allegations contained in paragraphs 104 and 105 of the complaint.

SPECIFIC FACTUAL ALLEGATIONS

56. Defendants are without specific information on which to admit or deny the allegations contained in paragraph 106 of the complaint, and therefore deny the same and puts plaintiff to his strict burden of proof.

FIRST CAUSE OF ACTION
STRICT LIABILITY

57. In response to paragraph 107 of the complaint, defendants restates, realleges, and incorporates by reference paragraphs 1 through 106 of its answer to the complaint.

58. In response to paragraph 108 of the complaint, defendants admit part of the allegations and deny part of the allegations, and affirmative allege that (1) Johnson &

Johnson Pharmaceutical Research & Development, LLC did research, development and testing on Levaquin®; (2) Johnson & Johnson Pharmaceutical Research & Development, LLC did not manufacture, market, sell or distribute Levaquin®; (3) Johnson & Johnson did not design, test, manufacture, market, sell or distribute Levaquin®; and (4) Levaquin® is a product of Ortho-McNeil. Defendants deny the remaining allegation contained in paragraph 108 of the complaint.

59. In response to paragraph 109 of the complaint, defendants affirmatively allege that they have no knowledge of the condition of the product after it was sold.

60. Defendants deny the allegations contained in paragraph 110 of the complaint.

61. In response to paragraph 111 of the complaint, defendants are without sufficient information to admit or deny the allegation that plaintiff used Levaquin in the manner for which it was intended, and therefore deny the same and puts plaintiff to his strict burden of proof. Defendants deny the remaining allegations contained in paragraph 111 of the complaint.

62. Defendants deny the allegations contained in paragraph 112 through 119 of the complaint.

SECOND CAUSE OF ACTION
NEGLIGENCE

63. In response to paragraph 120 of the complaint, defendants restate, reallege, and incorporate by reference paragraphs 1 through 119 of their answer to the complaint.

64. In response to paragraph 121 and 122 of the complaint, defendants state that the allegations contained therein call for a legal conclusion to which no response is necessary, but responding further defendants deny those allegations to the extent they seek to impose obligations on defendants beyond those required by law.

65. Defendants deny the allegations contained in paragraph 123 through 127 of the complaint.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

66. In response to paragraph 128 of the complaint, defendants restate, reallege, and incorporate by reference paragraphs 1 through 127 of their answer to the complaint.

67. In response to paragraph 129 of the complaint, defendants admit part of the allegations and deny part of the allegations, and affirmative allege that (1) Johnson & Johnson Pharmaceutical Research & Development, LLC did research, development and testing on Levaquin®; (2) Johnson & Johnson Pharmaceutical Research & Development, LLC did not manufacture, market, sell or distribute Levaquin®; (3) Johnson & Johnson did not design, test, manufacture, market, sell or distribute Levaquin®; and (4) Levaquin® is a product of Ortho-McNeil. Defendants deny the remaining allegation contained in paragraph 108 of the complaint.

68. In response to paragraph 130 of the complaint, defendants state that the allegations contained therein call for a legal conclusion to which no response is necessary, but responding further defendants deny those allegations to the extent they seek to impose obligations on defendants beyond those required by law.

69. In response to paragraph 131, defendants are without sufficient information to admit or deny the allegations of this paragraph and therefore deny the same and puts plaintiff to his strict burden of proof.

70. Defendants deny the allegations contained in paragraph 132 through 134 of the complaint.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES

71. In response to paragraph 135 of the complaint, defendants restates, reallege, and incorporate by reference paragraphs 1 through 134 of their answer to the complaint.

72. Defendants deny the allegations contained in paragraph 136, 137 and 139 of the complaint.

73. Defendants deny the allegations contained in paragraph 138 of the complaint and deny that it extended any express warranties to plaintiff.

FIFTH CAUSE OF ACTION
FRAUD

74. In response to paragraph 140 of the complaint, defendants restate, reallege, and incorporate by reference paragraphs 1 through 139 of their answer to the complaint.

75. Defendants deny the allegations contained in paragraph 141 and 143 through 157 of the complaint.

76. Defendants deny the allegations contained in paragraph 142 of the complaint and state that serious as well as minor side effects, including tendon rupture, have been reported in conjunction with the use of all quinolones, including Levaquin. Defendants further state that the FDA approved prescribing information for Levaquin has at all times contained the appropriate information for the prescribing physician.

SIXTH CAUSE OF ACTION
UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

77. In response to paragraph 158 of the complaint, defendants restate, reallege, and incorporate by reference paragraphs 1 through 157 of their answer to the complaint.

78. Defendants deny the allegations contained in paragraph 159 through 163 of the complaint.

SEVENTH CAUSE OF ACTION
PUNITIVE DAMAGES

79. In response to paragraph 164 of the complaint, defendants restate, reallege, and incorporate by reference paragraphs 1 through 163 of their answer to the complaint.

80. Defendants deny the allegations contained in paragraph 165 through 167 of the complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The complaint fails to state a claim upon which relief may be granted against defendants.

SECOND AFFIRMATIVE DEFENSE

Johnson & Johnson is not a proper party to this lawsuit.

THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by the applicable statutes of limitations.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff knowingly, intentionally and voluntarily assumed any and all risks inherent in the use of the product and/or was contributorily negligent, which conduct is a complete bar to his recovery, if any.

FIFTH AFFIRMATIVE DEFENSE

If plaintiff sustained any of the injuries alleged in the complaint, which is denied, there was an intervening cause and/or causes leading to said alleged injuries, and as such, any action on the part of defendants was not the proximate and/or competent producing cause of plaintiff's alleged injuries.

SIXTH AFFIRMATIVE DEFENSE

If plaintiff sustained any of the injuries alleged in the complaint, which is denied, said injuries were caused in full or in part by the conduct of one or more third persons for whose conduct defendants are not responsible or with whom defendants has no legal relation.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's alleged injuries, if any, were caused in whole or in part by pre-existing conditions.

EIGHTH AFFIRMATIVE DEFENSE

Defendants are entitled to the benefit of all defenses and presumptions which may arise because the design, manufacture, inspection, packaging, issuing of warnings and instructions and/or labeling of the product, which is the subject of the complaint, were in conformity with the generally recognized, reasonably available and reliable state of the art and prevailing standards in the industry at the time the product was manufactured.

NINTH AFFIRMATIVE DEFENSE

At all relevant times, defendants presumptively exercised due care, any product (if involved herein, which is denied) was presumptively not defective, and the warnings and instructions relating to its products were presumptively adequate, because defendants' conduct, any products, and warnings and instructions were governed by and conformed with the Food, Drug and Cosmetic Act, and other applicable federal statutes, rules and regulations.

TENTH AFFIRMATIVE DEFENSE

Plaintiff's recovery, if any, must be diminished in proportion to any culpable conduct in accordance with C.P.L.R. § 1411.

ELEVENTH AFFIRMATIVE DEFENSE

Pursuant to C.P.L.R. §§ 1601 and 1602, although defendants deny that they are liable herein, to the extent defendants are held liable to plaintiff, their share of the damages should be limited in accordance with any relative culpability.

TWELFTH AFFIRMATIVE DEFENSE

Plaintif's claims for the cost of medical care, rehabilitation services, loss of earnings or other economic loss is subject to the provisions of C.P.L.R. § 4545 and any such past or future costs or expenses which were or will be replaced or indemnified, in whole or in part, from any collateral source are not recoverable in this action.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent plaintiff has or will settle with any defendants or any other person with respect to the allegations in the complaint, the liability of defendants, if any, shall be reduced pursuant to section 15-108 of the General Obligations Law.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff knowingly, intentionally and voluntarily assumed any and all risks inherent in the use of the product and/or were contributory negligent and/or engaged in misuse or abuse of said product, which conduct is a complete bar to plaintiff's recovery, if any.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims based on any alleged duty to warn are barred because the prescribing physician was a learned intermediary.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff's strict liability claims are barred by the unavoidably dangerous product defense stated in Restatement (Second) of Torts § 402A, Comment k.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's defects claims are barred by Sections 2, 4, and 6(c) and (d) of the Restatement (Third) of Torts: Products Liability.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are preempted, in whole or in part, by federal law under the Supremacy Clause of the United States Constitution

NINETEENTH AFFIRMATIVE DEFENSE

The product at issue in this case fall under the auspices of the Food, Drug and Cosmetic Act and regulations promulgated by the federal Food and Drug Administration, and all causes of action are therefore preempted by Federal Law. *See* 21 U.S.C. §§ 301 to 399. Fed. Reg. 3922 (January 24, 2006).

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because any alleged representations with respect to the product were not false or misleading and constitute protected speech under the applicable provisions of the United States Constitution, including the First Amendment, and analogous provisions of the New York constitution.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because the utility of the product as marketed and sold outweighs its risks.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff has failed to mitigate his damages, if any, despite full knowledge of them.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Defendants hereby gives notice that they intend to rely on such other affirmative defenses as may become available or apparent during the course of discovery and reserve the right to amend their answer to assert any such defense.

Dated: New York, New York
May 1, 2008

PATTERSON BELKNAP WEBB & TYLER LLP

By: _____
John D. Winter
A Member of the Firm
Attorneys for Defendants
1133 Avenue of the Americas
New York, New York 10036-6710
Telephone: (212) 336-2000

TO: LEWIS SAUL & ASSOCIATES, PC
Lewis J. Saul
Attorneys for Plaintiff
29 Howard Street, #3
New York, NY 10013
Phone: (212) 226-3413